510(k) Summary
Life Spine Anterior Lumbar Plate System (Presidio)

Submitted By: Life Spine, Inc.
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Date Prepared: August 15th, 2013

Trade Name: Anterior Lumbar Plate System (Presidio)

Common Name: Spinal Fixation System

Classification: KWQ, CFR 888.3060, Class II

Predicate Device: Life Spine Anterior Lumbar Fixation System (K093200)
Blackstone Unity Anterior Lumbar Fixation System (K043548)

Device Description:

The Presidio Anterior Lumbar Fixation System consists of a variety of plates and screws to suit the individual pathology and anatomical conditions of the patient. All components are fabricated and manufactured from titanium alloy 6AL-4V-ELI per ASTM F-136.

The plates are manufactured in a variety of configurations with options including lengths of 32mm-53mm lengths and curvature of R 50mm, 100mm, and 250mm. The screws are manufactured in variable and fixed configurations with diameters of 5.5mm and 6.5mm and lengths of 18mm-40mm. The lock plate is manufactured in one size to fit with all plate lengths. The responsible surgeon will determine the correct size of the implant in accordance with the size of the individual patient.

The Presidio Anterior Lumbar Fixation System also utilizes a variety of standard orthopedic instruments to assist in the placement of the devices.

Intended Use of the Device:

The Life Spine Anterior Lumbar Fixation System (Presidio) is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

Technological Characteristics:

The Life Spine Anterior Lumbar Fixation System (Presidio) is substantially equivalent to the predicate system in terms of design, materials, indications for use and sizing.

Material:

The Life Spine Compression Plate material is 6AL-4V-ELI titanium manufactured according to ASTM F136. The device is comprised of a variety of non-sterile, single use components.

Performance Data:

Static compression, static torsion, dynamic compression and screw push out testing per ASTM F1717 was presented to demonstrate the substantial equivalency of the Life Spine Anterior Lumbar Fixation System (Presidio).

Conclusion:

The information presented demonstrates the substantial equivalency of the Life Spine Anterior Lumbar Fixation System (Presidio)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 8, 2013

Life Spine, Incorporated
Mr. Randy Lewis
Director of RA/ QA
2401 West Hassell Road, Suite 1535
Hoffman Estates, Illinois 60169

Re: K132589
Trade/Device Name: Life Spine Anterior Lumbar Fixation System (Presidio™)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 6, 2013
Received: September 9, 2013

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132589

Device Name: **Life Spine Anterior Lumbar Fixation System (Presidio™)**

Indications for Use: The **Life Spine Anterior Lumbar Fixation System (Presidio)** is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices